

USSN: 10/809,176

Attorney Docket: 2003.002 US

Response to Office Action of March 22, 2007

REMARKS

In the Office Action of March 22, 2007, the Examiner objected to the specification for including an embedded hyperlink. With the present amendments to the specification this reference is deleted.

The Examiner objected that the disclosure requires a description of the drawings. With the present amendments to the specification the description of the drawings is now included.

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, although recognized as being enabling for an IBDV mutant comprising a mutation at position 222 as well as nucleotide sequence SEQ ID NO. 1 at positions 318-323, it is alleged that it does not reasonably provide enablement for a broad scope of “one or more mutations” that would enable the IBDV mutant to also successfully bind to moab B69 as well as moab 67.

The rejection of claim 1-10 under 35 U.S.C. § 112, first paragraph, for lack of enablement is respectfully traversed. The Examiner’s attention is directed to paragraphs [0023] through [0030]. In addition, Table 2 provides specific amino acids to be substituted at specific locations to provide a moab 67 epitope, as well as moab 57 and R63 epitopes. For example, proper folding for a 67 epitope was found only when the amino acid at position 222 (proline) was changed to serine or threonine. (paragraph 0027).

Similarly, Table 4 illustrates results of site directed mutagenesis whereby particular sequences at specific places resulted in epitopes reactive with particular antibodies, including the targeted, B69, 67 and R63. In addition, as taught in the specification, the deposits of cell lines expressing these monoclonal antibodies at the ATCC are identified in the specification.

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Contrary to the Examiner's assertion, Applicants have supplied clear teachings and specific descriptions of a variety of point mutations for mutant viruses according to the invention.

Applicants are not required to provide a sequence for every possible example of the claimed invention. It is respectfully submitted that Applicants have gone beyond the basic enablement requirement in providing a variety of examples of specific sequences to be substituted in specific locations in the virus to obtain mutant virus according to the invention.

With the regard to the question regarding undue experimentation, Applicants have provided more than sufficient directions to the skilled practitioner. For example, the claimed viral mutants are defined by binding patterns with specific monoclonal antibodies. These can easily be tested by the least skill practitioner.

The Examiner objected that hybridoma HB-11122, secreting moab 67, needs to be deposited in order to be available to support the enablement requirement. Submitted herewith is a copy of a letter which, by return signature, acknowledged the availability of the HB-10157 and HB-11122 and that all restrictions on availability had been irrevocably been removed according to the requirements of the United States Patent and Trademark Office, signed by Barbara M. Hailey of the ATCC Patent Depository on January 23, 1998. This is in reference to the issuance of U.S. Patent 5,632,989. Also, submitted is a letter to Barbara Hailey from Steven B. Kelber advising her that the '989 patent had issued and that all restrictions on the deposits, including HB-11122, be removed immediately, noting that the deposits were made pursuant to the Budapest Treaty. Accordingly, the requirements for public availability had been met through the Budapest Treaty Deposit and the issuance of the '989 patent. Mr. Kelber's letter instructs the ATCC to remove all restrictions on the HB-11122 deposit on behalf of the depositors, assignee of the '989 patent, withdrawing all restrictions, irrevocably.

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Therefore, the requirement that someone associated with the patent owner who is in a position to make such assurances, in this case the attorney of record, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions on the availability to the public are irrevocably removed has been met.

Claims 7-10 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner objected to claim 7 for reciting a vaccine for use in the protection of poultry caused by IBDV infection.

Applicants respectfully traverse the rejection for lack of enablement in view of example 4, which does show that after challenge with a pathogenic field isolate no challenge virus could be detected in any of the bursae derived from chickens vaccinated with the inactivated IBDV vaccine according to the invention, while those vaccinated with inactivated IBDV D78 vaccine did show the presence of challenge virus [0148]. As stated, the results obtained in this experiment indicated that the inactivated IBDV and GB02 vaccine [according to the invention] provide chickens with a solid protection against infection with the IBDV GB02 field isolate. [0149].

However, in order to advance the prosecution of this application, Applicants have amended claims 7-10 to be directed to immunogenic compositions, which are clearly shown in the examples provided. Applicant has canceled claims 11-19 without prejudice or disclaimer of the subject matter thereof.

In view of the above, it is believed that claims 1-10 are in condition for allowance. Favorable action is solicited. Should the Examiner consider that a conference would be helpful in advancing the prosecution of this application, he is invited to telephone Applicants' attorney at the number below.

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Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **02-2334**.

Respectfully submitted,



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WMB:dap

Enclosures (2): Acknowledgement by B. Hailey signed on January 23, 1998 (1 page)
Correspondence from S. B. Kelber of January 22, 1998 (1 page)